UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,029	07/29/2003	Rajinder Singh	28575/US/US	3056

25763 7590 08/22/2005

DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
50 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402-1498

EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,029	SINGH ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *All*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-48 are presented for examination.

Applicants' drawings filed July 29, 2003 and the information disclosure statements filed January 7, 2004; February 7, 2004; August 3, 2004 and December 27, 2004 have been received and entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9-29, 31-36, 45, 47, 49 and 50 of copending Application No. 10/355,543. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application, 10/355,543 teaches compounds and compositions comprising 2,4-pyrimidinediamine derivatives of formula I; and the present application teaches a method of use claims containing the instant compounds or composition of the copending application therein which makes the compounds and composition claims of the copending application an obvious variation of the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-48 are not allowed.

Claims 1-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-24 and 26-29 of copending Application No. 10/858,343. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application, 10/858,343 teaches compounds and compositions comprising 2,4-pyrimidinediamine derivatives of formula I; and the present application teaches a method of use claims containing the instant compounds or composition of the copending application therein which makes the compounds and composition claims of the copending application an obvious variation of the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-48 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating autoimmune diseases with a 2,4-pyrimidinediamine compounds of structural formula (I), does not reasonably provide

enablement for preventing autoimmune diseases with a 2,4-pyrimidinediamine compounds of structural formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method of preventing an autoimmune disease and/or one or more symptoms associated therewith, comprising the step of administering to a subject suffering from an autoimmune disease or at risk of developing an autoimmune disease an effective amount of a 2,4-pyrimidinediamine compound according to structural formula (I) of claim 1.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

There are no known preventive therapies for autoimmune diseases in the art.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive to all autoimmune diseases can be treated and prevented with all the derivatives from the 2,4-pyrimidinediamine compound of claim 1.

The amount of direction or guidance provided and the presence or absence of working examples

There are no examples showing the instant 2,4-pyrimidinediamine compounds of structural formula (I) of claim 1 will, in fact, prevent an autoimmune disease especially in a subject not presently at risk of or predisposed to developing such a disease.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular cause would be prevented for an autoimmune disease. The skilled artisan would expect that interaction of a particular drug in the prevention of an autoimmune disease to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis of the agent. The instant specification set forth no such understanding or any criteria for extrapolating beyond the administration of a 2,4-pyrimidinediamine compound of claim 1 to treat the said autoimmune diseases. Even for the data presented, no direction is provided to prevent an autoimmune disease and its causes. Absent reasonable *a priori* expectation of success, one skilled in the art would have to test extensively many conditions that may lead to the specific autoimmune disease of claims 1 and 43-48 to discover which cause is prevented. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as its is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Claims 1-48 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al. (5,958,935) of PTO-1449.

Davis et al. teach substituted 2-anilinopyrimidines, derived from the same 2,4-pyrimidineamine structural formula (I) as applicants' claim 1, are useful in the prophylaxis and treatment of immune diseases and are administered therapeutically. Note particularly column 8, lines 59-67 and column 9, lines 1-15 teaches the same compounds as applicants' preferred compounds disclosed in claim 39. Column 9,lines 23-28 teaches the various types of autoimmune diseases that are treated with the said compounds such as rheumatoid arthritis, multiple sclerosis and systemic lupus erythematosis (same as applicants' claims 45-48). Also note in column 9, lines 35-41; the compounds are administered as pharmaceutical compositions, which comprises the compounds together with a pharmaceutically acceptable carriers, excipients or diluents. Clearly, the cited reference anticipates the applicants' instant invention; therefore, the instant invention is unpatentable.

Claims 1-48 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
August 18, 2005